The opinion in support of the decision being entered today was ***not*** written for publication and is ***not*** binding precedent of the Board.

Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

GORDON V. VEHAR, DANIEL J. CAPON, RICHARD M. LAWN, WILLIAM I. WOOD, CORNELIA M. GORMAN, DANIEL L. EATON and ARTHUR D. LEVINSON
Junior Party[1]

v.

JOHN J. TOOLE, JR.
Senior Party[2]

Interference No. 103,215

HEARD: 31 JANUARY 2003

FINAL DECISION

Before CAROFF, METZ, and LORIN, Administrative Patent Judges.

METZ, Administrative Patent Judge.

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[1] Application Serial Number 07/584,076, filed September 18, 1990. Accorded benefit of U.S. Serial Number 06/907,297, filed on September 12, 1986, and now abandoned. Assigned to Genentech Inc., a Corporation of California.

[2] Application Serial Number 07/010,085 filed on April 11, 1986, now U.S. Patent Number 4,868,112, issued September 9, 1989. Accorded benefit of U.S. Serial Number 06/725,350, filed April 12, 1985. Assigned to Genetics Institute, Inc., a Corporation of Delaware.

The subject matter being contested in this proceeding is directed to certain biological materials. Specifically, this proceeding is directed to recombinant DNA and to a variant of human protein. DNA is a natural biological material made up from individual compounds known as nucleotides arranged in a particular order known as a sequence. Recombinant DNA is DNA synthesized by combining together segments from one or more DNA molecules to form a new DNA molecule. Proteins are polymeric molecules known as peptides made up of repeating units of amino acids arranged in a particular order. For an excellent discussion of the relationship between DNA and proteins we direct attention to Judge Rich's opinion in In re O'Farrell, 853 F.d. 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir. 1988).

A naturally occurring protein known as factor VIII protein is a clotting component of human blood. The primary structure of factor VIII protein consists of 2332 amino acids comprising three distinct structural domains: the A; B; and C domains. The B domain has been found to be lost when factor VIII protein is activated by thrombin, which processes factor VIII to active subunits. Like all proteins, factor VIII protein is obtained when a particular DNA which encodes factor VIII protein expresses the protein. The parties do not dispute that it was the assignee of the junior party, Genentech, which discovered the full length

recombinant DNA which encoded factor VIII protein. As noted above, researchers observed that the B domain was removed or cleared from factor VIII protein during processing in the human body, yet the protein expressed still retained its ability to clot blood. Based on the mechanism of natural processing it was therefore believed that less than the complete or full length DNA encoding factor VIII protein would encode a less than full length protein which still would possess the function of the full length protein, that is, blood clotting ability. Because the full length DNA and the protein encoded by the full length DNA are large molecules, and because it is easier to administer smaller molecules, it was desirable from the standpoint of the use and administration of these biological materials for human therapy to make smaller, easier to administer molecules which nevertheless retained the utility of the larger molecules.

This proceeding is directed to those shorter length (smaller) biological materials. Count 1 is directed to a recombinant DNA which upon expression results in a truncated or shortened factor VIII protein which possesses procoagulant activity (that is, upon further processing it yields a protein which is a blood coagulant) and which possesses a particular amino acid sequence. Count 2 is directed to an isolated and

purified human factor VIII protein having less than the complete amino acid sequence of full length factor VIII protein. The protein of Count 2 may be prepared in any fashion, including recombinantly, as by expression of the protein using the recombinant DNA of Count 1, or by enzymatic cleavage of naturally occurring full length factor VIII protein with subsequent isolation and purification of that cleaved protein.

The specific interfering subject matter contested by the parties in this proceeding is defined by two counts in this interference: Count 1, directed to recombinant DNA; and, Count 2, directed to an isolated and purified human protein variant. A copy of the counts is reproduced below for a more facile understanding of the contested subject matter in this interference.

COUNT 1

> A recombinant DNA which upon expression results in a truncated factor VIII protein which is an active procoagulant wherein the recombinant DNA encodes for a protein having the amino acid sequence of a human factor VIII:C except for having a deletion corresponding to at least 581 amino acids or at least 807 amino acids within the region between **Arg**-759 and **Ser**-1709 wherein the amino acid numbering is with reference to the **Met**-1 of the human factor VIII:C leader sequence.

COUNT 2

> An isolated and purified human factor VIII variant having a deletion of amino acids within the region from residue 741 to residue 1689, inclusive, wherein the amino acid numbering is with reference to **Ala**-1 of the mature human factor VIII:C sequence.[3]

The claims of the parties which correspond to Count 1 are:

Vehar et al.: Claims 38, 41 and 51 through 53
Toole, Jr.: Claims 1 through 9

The claims of the parties which correspond to Count 2 are:

Vehar et al.: Claims 22 through 30, 47, 54 and 55
Toole, Jr.: Claims 10 and 11

Both parties appeared at final hearing represented by their respective legal counsel. Both parties filed a record with associated exhibits.[4] No issue of interference-in-fact is raised by the parties in this proceeding.

THE PROCEEDINGS BELOW

This interference was declared on January 5, 1994, and was captioned as Toole, Jr., junior party, versus Vehar et al., senior party. During the preliminary motions period Toole, Jr.

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[3] See pages 7 and 8 of Vehar et al.'s brief for an explanation of the different conventions used to number the amino acid sequences in Counts 1 and 2.

[4] References to the Vehar et al. record will be designated as **VR**, followed by the record page number, and references to the Vehar et al. exhibits will be designated **VX**, followed by the exhibit number. References to the Toole, Jr. record will be designated as **TR** followed by the record page number. References to the Toole, Jr. exhibits will be designated by **TX** followed by the exhibit number.

filed, *inter alia*, a motion pursuant to 37 C.F.R. 1.633(g) to deny Vehar et al. the benefit of the earlier filing date accorded them when this interference was declared. Toole, Jr.'s motion was granted and as a result of the granted motion, Toole, Jr. became the senior party in this proceeding and Vehar et al. became the junior party. See Paper Number 31.

On February 27, 2001, the Administrative Patent Judge (APJ) handling the interlocutory phase of the interference issued an order including, *inter alia*, an opportunity for the parties to file a paper under 37 C.F.R. § 1.640(b) identifying any matters raised in the preliminary motions which the parties wished to have considered at final hearing. See Paper Number 43. On March 27, 2001, Toole, Jr. filed a paper listing the issues he wanted to address at final hearing (see Paper Number 47). On March 26, 2001, Vehar et al. filed a paper stating that there were no issues which were raised in the decision on preliminary motions which they wished to address at final hearing (see Paper Number 48).

During the testimony periods, the parties represented to the APJ that the parties had re-instituted previously abandoned settlement negotiations in their hopes of settling this proceeding without the need for a final hearing. In accordance with the parties' good faith representations, the APJ approved

several requested extensions of time of certain dates in the testimony schedule to accommodate the parties' settlement negotiations. Nevertheless, the parties's settlement negotiations were unsuccessful and a final hearing to determine priority was scheduled. The final hearing was held on January 31, 2003.

THE MOTIONS TO SUPPRESS

The parties have each filed several motions to suppress evidence pursuant to 37 C.F.R. § 1.656(h). Specifically, Vehar et al. have filed 4 (four) motions to suppress evidence: (1) a motion to suppress in its entirety the declaration and testimony of Dr. Fay; (2) a motion to suppress all evidence taken during the testimony period by Toole, Jr. and relied on by Toole, Jr. for any purpose other than proving his case for priority; (3) a motion to suppress Toole, Jr. Exhibits 2930 through 2933; and, (4) a motion to suppress Toole, Jr. Exhibits 3336 through 3340. Toole, Jr. has filed 3 (three) motions to suppress evidence: (1) a motion to suppress the notebook pages of Comstock (**VX** 340-41, 588-89, 622-26, 628, 630-33, 635-52 and 708-722) and Souder (**VX** 339, 564, 617, 627 and 629) and the testimony related to said notebooks; (2) a motion to suppress certain rebuttal evidence (**VX** 2967 through 2973 and 2979 through 2986) and the testimony related thereto (**VR** 1520 through 1524 and 1526 through 1530); and, (3) a motion to suppress the declarations of Eaton and Hass.

VEHAR ET AL.'S MOTIONS TO SUPPRESS

In their first motion to suppress, Vehar et al. move to suppress the declaration and deposition testimony of one of Toole, Jr.'s witness, Dr. Fay, on the grounds Dr. Fay was not qualified to testify as an expert on Coatest assays pursuant to the Federal Rules of Evidence, Section 702 (**FRE** 702). For reasons which follow, the motion to suppress is DENIED.

We find from the facts set forth in the declaration of Dr. Fay, which facts are not challenged by Vehar et al., that Dr. Fay is an expert in the field of human factor VIII protein. It is also clear from the undisputed facts that, in his role as an active researcher in human factor VIII protein, Dr. Fay conducted or had conducted on his behalf and under his supervision extensive research in measuring the activity of human factor VIII proteins. While Dr. Fay candidly admitted he never personally ran a Coatest assay (**VR** 222, lines 5 through 11), a particular, commercially available chromogenic assay kit, he also testified that he had run and interpreted other similar factor VIII chromogenic assays (**VR** 287, lines 5 through 25).

Vehar et al.'s motion frames the issue here as being whether or not Dr. Fay is an expert in Coatest assays. We find that casts the issue too narrowly. In our view, Dr. Fay's credentials and *curriculae vitae* establish him to be an expert in the structure,

function and regulation of human factor VIII protein, and establishes him as actively engaged in research involving human factor VIII protein. While not an "expert" in Coatest assays, specifically, Dr. Fay is nevertheless familiar with various chromogenic assays, including Coatest assays.

Additionally, Vehar et al. have argued that running a Coatest assay on a sample was a "perfunctory task", neither new nor unpredictable and as simple as removing an assay kit from a refrigerator and testing a sample according to the kit instructions. Indeed, in their opposition to Toole, Jr.'s motions to suppress (Paper Number 118) Vehar et al. have made the following observations about the Coatest assay:

> A Coatest assay is not an experiment but a simple routine test. Little or nothing about it is experiment-like. One simply adds store-bought reagents to a sample and watches whether it turns yellow.

The assay kits are therein further described as "being kept at Genentech in a refrigerator, like so many cans of Coke." See page 26 of paper Number 118. See also Vehar et al.'s reply brief at pages 53 and 57 through 58. Thus, as an expert in human factor VIII protein we do not consider Dr. Fay to be unqualified to testify about chromogenic assays of human factor VIII protein in general or the Coatest assay of human factor VIII protein in particular.

The arguments made by Vehar et al. concerning Dr. Fay's

familiarity or lack of familiarity with the Coatest assay go more to the weight we should accord his testimony on this specific issue rather than to whether or not we should exclude it. We find the discussion in Dr. Fay's testimony concerning the use of standards and controls in the Coatest assay to reflect the common sense, ordinary action and reasonable desire of any prudent researcher to ensure confidence in the results of his or her test data. The question of whether or not adequate controls or standards were run in a particular assay sufficient to render the results obtained reliable is a question of fact to be determined based on the evidence.

Further, while Vehar et al. have moved to exclude Dr. Fay's declaration and deposition testimony, they nevertheless rely extensively on Dr. Fay's declaration and testimony in their brief and reply brief in support of their case for priority. See pages 19 through 22; 64 through 69; 71 through 76; and, 79 and 80 of Vehar et al.'s brief and reply brief at pages 43, 44 and 63. It is at least inconsistent for Vehar et al. to request exclusion of Dr. Fay's testimony and to also rely on his testimony to prove their case. Therefore, for all the above reasons, the motion is denied.

Vehar et al.'s second motion to suppress is DISMISSED. Although Toole, Jr. indicated in his statement under 37 C.F.R.

§ 1.640(b) that he would raise at final hearing the propriety of the APJ's decision on motions with respect to certain Toole, Jr. motions which were denied, Toole, Jr. has chosen not to raise any of the denied motions in his brief. Rather, he has specifically stated in his opposition to the motion to suppress that he "will not request Board review at Final Hearing of Decisions on Toole's Preliminary Motions." See page 2 of Paper Number 111. Accordingly, the relief requested by Vehar et al. is rendered moot.

Vehar et al.'s third and fourth motions to suppress seek to exclude certain Toole, Jr. exhibits. Specifically, the third motion seeks to exclude certain inserts to Dr. Gorman's laboratory notebook and certain letters of correspondence between the parties' respective lead counsel on the grounds they are hearsay and on the grounds that the letters of correspondence have not been properly introduced into the record. Vehar et al's fourth motion seeks to exclude certain Toole, Jr. exhibits on the grounds that the exhibits have never been introduced into evidence pursuant to 37 C.F.R. § 1.671(e).

The third and fourth motions to suppress are DISMISSED. As noted by Vehar et al. in their motion and as conceded by Toole, Jr. in his opposition, neither the inserts to Dr. Gorman's notebook nor the letters of correspondence between the parties'

legal representatives was properly introduced into the record according to the procedures set forth in 37 C.F.R. § 1.671(e). Therefore, the exhibits which Vehar et al. seek to suppress are not of record in the sense of the rule. Our authority under 37 C.F.R. 1.656(h) does not extend to evidence which is not of record.

TOOLE, JR.'S MOTIONS TO SUPPRESS

The motion to suppress the notebooks of Comstock and Souder on the grounds they are impermissible hearsay is GRANTED. Vehar et al. do not argue that the materials whose exclusion is sought are not hearsay. Rather, Vehar et al. argue that: (1) Toole, Jr. has waived any right to object to the notebooks; (2) the notebooks are admissible under a certain exception found in the **Federal Rules of Evidence** (**FRE**) to the hearsay rule (**FRE** 802); (3) the notebooks are admissible under the so-called "rule of reason"; (4) no adverse inference may be drawn from the failure of Comstock and Souder to testify; (5) Dr. Gorman adequately explained the content of the Comstock and Souder notebooks; and, (6) case law supports denying the motion to suppress.

The first sentence of 37 C.F.R. § 1.671(b) recites that: "(e)xcept as otherwise provided in this subpart, the Federal Rules of Evidence shall apply to interference proceedings." **FRE** 802, which is captioned "**Hearsay Rule**" reads as follows:

> Hearsay is not admissible except as provided by these rules or by other rules prescribed by the Supreme Court pursuant to statutory authority or by Act of Congress.

and applies to any evidence presented and relied on by the parties. Hearsay is defined in part (c) of **FRE** 801 (captioned **"Definitions"**) as:

> `Hearsay' is a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted.

Part (a) of **FRE** 801 defines "statement" as follows:

> A `statement' is (1) an oral or written assertion or (2) nonverbal conduct of a person, if it is intended by the person as an assertion.

It is against these definitions from the **FRE** that we shall consider the Toole, Jr. motions to suppress.

Toole, Jr., moves to suppress the exhibits which consist of various pages from the laboratory notebooks of Lisa Comstock and Jill Souder Dembroff[5] and all the testimony associated with their laboratory notebooks. As correctly observed by Toole, Jr., neither Ms. Comstock nor Ms. Dembroff testified in this proceeding. Dr. Gorman, one of the named co-inventors of Vehar et al.'s involved application, has testified extensively about Ms. Comstock's and Ms. Dembroff's alleged involvement in reducing to

[5] Apparently, Ms. Souder married at some time after her alleged notebooks were created.

practice a compound within one of the counts based on Dr. Gorman's affidavits from 2001 concerning the content of Comstock's and Souder's notebooks which are alleged to have been created in 1984. Vehar et al. rely on Dr. Gorman's testimony explaining the content of the laboratory notebooks and associated scientific data as evidence which considered together allegedly establishes an actual reduction to practice of the subject matter of the counts on a date prior to Toole, Jr.'s effective filing date of April 12, 1985.

We find that the laboratory notebooks and the associated scientific data are statements ("written assertions") other than one made by the declarant while testifying (Dr. Gorman) and which are being offered to prove the truth of the matter asserted (an actual reduction to practice prior to Toole, Jr.'s effective filing date). Thus, pursuant to 37 C.F.R. § 1.671(b) and **FRE** 802, we find the laboratory notebooks and the associated scientific data are hearsay. Vehar et al. do argue that the notebooks whose exclusion is sought are not hearsay.

Notwithstanding our determination above that the notebooks and associated scientific data are hearsay, they would not be excluded from the evidence if Vehar et al. could establish that they came within any of the hearsay exceptions set forth in **FRE** 803 (**Hearsay Exceptions; Availability of Declarant Immaterial**) or

FRE 807 (**Residual Exception**), formerly **FRE** 803(24). Vehar et al. argue that the notebooks should be admitted under **FRE** 807 notwithstanding that they are hearsay.

Vehar et al. argue that Toole, Jr. has waived any right to exclude the notebooks as hearsay because Vehar et al.'s objections to the evidence sought to be suppressed lacked the specificity required by 37 C.F.R. § 1.672(c). Specifically, Vehar et al urge that the nature of the objections made by Toole, Jr. to the Comstock and Souder notebooks were too general to satisfy the particularity required by the rule.[6]

Vehar et al.'s argued position lacks the citation to <u>any</u> authority which supports Vehar et al.'s interpretation of that rule. Additionally, implicit in Vehar et al.'s argument is the recognition that Toole, Jr. has objected to the notebooks as hearsay, albeit they believe without sufficient specificity. We find Toole, Jr.'s objection was adequate to place Vehar et al. on notice that Toole, Jr. believed the notebooks to be hearsay. Vehar et al.'s observation that Toole, Jr.'s objections in Paper Number 61 are limited to declaration testimony is not entirely understood. In the first instance, § 1.672(c) <u>is</u> directed to

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[6] On page 11 of their motion to suppress, Vehar et al. incorrectly cite 37 C.F.R. § 1.672(b) as the section of the rule wherein the requirement for an objection "stating with particularity the nature of each objection" may be found rather than § 1.672(c) where the language is actually found. See Paper Number 118.

testimony taken by affidavit (declaration). Moreover, Toole, Jr. did object to entries in the Comstock and Souder notebooks as hearsay (see page 18 of Paper Number 61, for example). Toole, Jr.'s timely objection on the record for any reason under the **FRE** and the interference rules was all that was required under 37 C.F.R. § 1.656(h) to preserve his right to move to exclude the exhibits in question. It is Toole, Jr.'s motion which must set forth with adequate specificity the reasons why the relief requested should be granted. We find Toole, Jr.'s objection to the notebooks as hearsay was adequately specific and that there was no "waiver" by Toole, Jr. of his right to move to suppress the notebooks and related testimony.

Vehar et al.'s reliance on **FRE** 807 as an exception to the hearsay rule under which the notebooks are admissible notwithstanding that they are hearsay is unavailing. In order to be admissible under **FRE** 807 we must, in the words of Part (B) of the rule, find that;

> the statement is more probative on the point for which it is offered than any other evidence which the proponent can procure through reasonable efforts ...

We find that the testimony of Comstock and Souder explaining the content of their notebooks and their recollection of what they did to produce the content of the notebooks would be far more probative than the notebooks themselves or Dr. Gorman's testimony

more than 16 (sixteen) years after-the-fact. The notebooks are collections of data, including handwritten notes using various acronyms, which are not self-explanatory. Dr. Gorman's testimony cannot and does not convert the Comstock and Souder notebooks from hearsay to admissible evidence. Moreover, as a named inventor of the involved Vehar et al. application and a presumed inventor of at least one Vehar et al. application claim designated as corresponding to the count, Dr. Gorman's testimony requires corroboration.[7] We find no corroboration of Dr. Gorman's testimony concerning the notebooks of Comstock and Souder.

Vehar et al.'s argument that neither Comstock nor Souder could add materially to what Dr. Gorman has testified to about the notebooks is sheer speculation, unsupported attorney argument and begs the question before us because we do not have Comstock's or Souder's testimony. While we draw no adverse inference from Comstock or Souder's failure to testify, neither will we surmise as to what, if called, they may have testified to. We do not accept Vehar et al.'s theory that both Comstock and Souder necessarily would have so little recollection about their work and their notebooks as not to add to Dr. Gorman's after-the-fact recollections made more than 16 (sixteen) years after the work

[7] We address in a separate section of our decision the question of inventorship of the subject matter of the counts.

was performed. Indeed, many of the notebook entries were made on dates (for example, **VX** 339, 564, 622-626) when Dr. Gorman was not yet employed by Vehar et al.'s assignee, Genentech! As between the testimony of Dr. Gorman, who with respect to at least certain of the notebooks sought to be excluded had not yet come to work for Genentech, and the testimony of Comstock and Souder, who actually performed the work and made the notebook entries whose admissibility is contested, we find the testimony of Comstock and Souder would be more probative.

We also agree with Toole, Jr. that **FRE** 807(B) requires that Vehar et al. must have made "reasonable efforts" to procure the testimony of Comstock and Souder to invoke the exception in **FRE** 807 and obtain the admission of the notebooks under **FRE** 807. While Vehar et al. allege that Comstock and Souder are "unavailable" as defined by **FRE** 804(a)(5) ("is absent from the hearing and the proponent of a statement has been unable to procure the declarant's attendance ... by process or other reasonable means"), we agree with Toole, Jr. that there is no evidence of what "reasonable efforts", if any, were taken by Vehar et al. to locate Comstock and Souder. We find it significant, as noted by Toole, Jr. in his reply at page 13 that Vehar et al. <u>were</u> able to locate 4 (four) witnesses who did testify and who no longer worked for Genentech but made,

apparently, no efforts to locate either Ms. Comstock or Souder.

Vehar et al.'s reliance on the decision by the United States District Court for the District of Delaware in Standard Oil Co. v. Montedison, S.P.A., 494 F.Supp 370, 206 USPQ 676 (D. Del. 1980), *aff'd.* 664 F.d. 356, 212 USPQ 327 (3d Cir. 1981) in support of their argument that the notebooks are admissible under **FRE** 807 is misplaced. In the first instance, neither the decision of the District Court nor the Court of Appeals for the Third Circuit is binding precedent on this Board. Further, in 1980 when the district court rendered its opinion and in 1981 when the circuit court of appeals rendered its opinion, the so-called "old interference rules" (37 C.F.R. § 1.200 *et seq.*) did **not** incorporate in interference proceedings the **FRE** as the "600" rules do now. Additionally, a proceeding under 35 U.S.C. § 146 is not an interference proceeding before the Board under 35 U.S.C. § 135(a) so the relevance of a district court's action in a *de novo* proceeding under § 146 to an interference proceeding in the Patent and Trademark Office (PTO) before the Board under § 135 is not apparent.

Vehar et al.'s reliance on Lacotte v. Thomas, 758 F.d. 611, 225 USPQ 633 (Fed. Cir. 1985) as a basis for denying Toole, Jr.'s motion to suppress is also misplaced. In the first instance, in Lacotte the interference proceeding before the Board was

conducted under the so-called "old rules" which did not incorporate the **FRE**. More significantly, the notebook page in question in Lacotte "was entered into evidence before the board" *id.*, and, accordingly, no question of admissibility of hearsay under one of the hearsay exceptions of the **FRE** was raised or decided in the cited case.

Vehar et al.'s argument that the so-called "rule of reason", a court-created doctrine for measuring the weight given to a party's admissible evidence of corroboration, "subsumes the hearsay rule" is unavailing and finds no basis in the cases cited by Vehar et al. for that proposition. The concepts of the admissibility of evidence and the weight given admissible evidence for the purposes of determining corroboration are separate and distinct issues. Admissibility goes to whether or not evidence which is properly authenticated (**FRE** 901) is relevant to an issue being decided (**FRE** 401) while corroboration goes to determining the veracity of the admissible evidence. Further, the evidence on which Vehar et al. seek to rely and whose admission Toole, Jr. seeks to suppress is not evidence relied on to corroborate an inventor's testimony but is, rather, the very evidence of an actual reduction to practice on which Vehar et al. rely to prove they are entitled to an award of priority.

Hurwitz v. Poon, 364 F.d. 878, 150 USPQ 676 (CCPA 1966) on which Vehar et al. rely is a case decided before the interference rules incorporated the **FRE**. Additionally, the court's observation concerning the so-called "rule of reason" and the application of the hearsay rule was made concerning the requirement for corroboration of an element of proof in the party Poon's priority case and did not involve a question of admissibility of particular evidence whose exclusion was sought by Poon's opponent. We consider the court's observation concerning the "rule of reason" and the admissibility of certain evidence to be limited to the particular facts of that case rather than the court pronouncing a general rule of law. Also, both the cases cited by the court in the quote from Hurwitz are directed to the requirements of corroboration not the admissibility of hearsay under **FRE** 807.

Likewise, Kridl v. McCormick, 105 F.3d 1446, 41 USPQ2d 1686 (Fed. Cir. 1997) on which Vehar et al. rely does not stand for the proposition urged by Vehar et al. Indeed, Kridl does not mention the application of the hearsay rule in any part of the opinion. Rather, Kridl went to the sufficiency (weight) the Board assigned to the evidence of McCormick's corroboration of conception. Since there was no challenge to any evidence on the grounds that the evidence was impermissible hearsay we do not

find Kridl to be relevant to the issue here presented by Toole, Jr.'s motion to suppress.

Borror v. Herz, 666 F.d. 569, 213 USPQ 19 (CCPA 1981), another "pre-600 rules" decision on which Vehar et al. also rely, is even farther removed from being relevant to the issue before us. Borror did not deal with admissibility of hearsay evidence but to the Board's finding that an inventor's testimony was so indispensable to proving priority for the party with the burden of persuasion that its absence, as a matter of law, necessarily defeated that party's case for priority. Indeed, the only relevant discussion by the court concerning hearsay may be found in footnote [5] at 666 F.d. 573, 213 USPQ 22 wherein the court advised:

> It is important to distinguish the present situation which involves testimony of witnesses not inherently objectionable as hearsay and a case where a party seeks to prove its case principally by such evidence. Where testimony of an inherently inferior nature is offered, a foundation must be laid in accordance with Fed. R. Evid. 804. While appellees here object to some of the testimony as hearsay, the board indicated that it gave such evidence little weight. We do not find reversible error in its ruling. (emphasis ours)

As recognized by the court from the footnote above and by Vehar et al. at page 18 of their opposition to the motion to suppress, Borror did not involve hearsay but the weight accorded properly authenticated, admissible documentary evidence.

Finally, Vehar et al. urge that we should admit the Souder and Comstock notebooks notwithstanding that they are hearsay because Dr. Gorman, the supervisor of both Comstock and Souder, has adequately explained the notebook entries. Vehar et al. rely on the decision in Holmwood v. Sugavanam, 948 F.d. 1230, 1236, 20 USPQ2d 1712, 1714 (Fed. Cir. 1991) in support of their position that the person who explains the relevance of documentary evidence (notebook) need not be the author of the document. We find Vehar et al.'s position to be entirely unpersuasive.

In the first instance, Holmwood did not involve a question of the admissibility of evidence let alone hearsay. Indeed, the testimony and test data which was objected to in Holmwood was admitted before the Board and formed no part of the court's decision. Holmwood attempted to prove prior invention by establishing introduction of an actual reduction to practice of the subject matter of the count into the United States before their opponents' filing date. Holmwood could not prove prior invention through acts in a foreign country because of the prohibition in 35 U.S.C. § 104. Holmwood's assignee routinely sent compounds prepared and tested for utility in Germany to their U.S. affiliate for confirmatory testing. The samples were sent to a Dr. Zeck, a non-inventor, for testing. Only Dr. Zeck

knew the identity of the compounds and the compounds were then given to technicians for blind-testing. Based on the results obtained by the technicians, Dr. Zeck testified that the compounds sent to him from Germany had been determined to possess the utility ascribed to them by the scientists in Germany. The Board found that the technicians who had conducted the tests but who had not testified were the most "satisfactory" witnesses not Dr. Zeck. The court simply held that Dr. Zeck was the most satisfactory witness to testify about the test results and that as a non-inventor the Board's characterization of his testimony as "not sufficiently corroborated" was "misplaced."

Here, unlike the facts in Holmwood, except for their belief that the sample being tested was a factor VIII-type protein neither Comstock, Souder nor Dr. Gorman knew the identity of the sample which they were "testing." That is, neither Comstock, Souder or Dr. Gorman isolated any protein expressed by the transfected cell and determined its amino acid sequence. Rather, they were looking for, and the Coatest assay only determined whether or not a protein in a given sample had particular activity. Further, unlike Dr. Zeck in Holmwood, Dr. Gorman is a named inventor of the involved Vehar et al. application and, therefore, her testimony requires corroboration. Additionally, as

we have noted above, Dr. Gorman was only employed by Genentech for several weeks when the Coatest assay results relied on for an actual reduction to practice were obtained and she was not an employee of Genentech when many of the laboratory notebook entries whose exclusion is sought were made by either Souder or Comstock. Thus, she did not possess the intimate knowledge possessed by Dr. Zeck which the court found to be so important in their decision. Holmwood, 948 F.d. at 1239, 20 USPQ2d at 1239.

Rather, in Alpert v. Slatin, 305 F.d. 891, 895-96, 134 USPQ 296, 300 (CCPA 1962), the court, in discussing whether or not reports of scientific research and testing were subject to the "shop book" rule of 28 U.S.C. 1732, characterized reports of the inventors to their superiors about the work the inventors allegedly performed and the reports of test data as being:

> no more than the usual inventor's work or progress reports which the decisions of this court have held cannot be relied on to establish reduction to practice since they are not independent corroboration of an inventor's testimony. (citations omitted)

Thus, the court reasoned that even if admissible, the weight given to such evidence is "no more than can be accorded to any other self-serving written document." *Id.*

In the commentary to the final rules published in the Federal Register on December 12, 1984, the PTO, in commenting on the adoption of the Federal Rules of Evidence in the "new"

interference rules, observed that:

> The courts have articulated a rule of law which the PTO will continue to apply in determining admissibility of laboratory note books under the "shop book" Rule 803(b)(6) of the Federal Rules of Evidence. See e.g., Alpert v. Slatin, 305 F.d. 891, 134 USPQ 296 (CCPA 1962) ...

See the Notice of Final Rule, Federal Register, Volume 49, Number 240, December 12, 1984, at page 48447. Accordingly, exclusion of the notebooks is consistent with the PTO's rulemaking authority as expressed in the commentary to the adoption of the final rules.

In light of our decision granting Toole, Jr.'s motion, in considering Vehar et al.'s case for priority we shall not consider any of the excluded evidence or any testimony elicited to explain the excluded evidence.

Toole, Jr.'s motion to suppress certain Vehar et al. rebuttal evidence is GRANTED-IN-PART. In their opposition to the motion, Vehar et al. state that: "Genentech does not oppose suppression of either **VX** 2979-86 or **VR** 1520-24 and 1526-30." (footnote omitted). Accordingly, the motion is granted to the extent that the aforementioned exhibits are suppressed. With respect to the suppression of **VX** 2967-73, Vehar et al. state they would not object to their suppression "if Dr. Fay's Declaration is suppressed", an event which has not occurred. Accordingly, we must address Vehar et al.'s argument that Toole, Jr. waived any

objection to these exhibits by failing to timely object to the exhibits during the cross examination deposition of Dr. Fay when they were presented.

Toole, Jr. argues that there was no waiver of any objection and that when Dr. Fay was presented the documents in question, counsel for Toole, Jr. objected to their admission as being offered too late in the testimony period and reserved Toole, Jr.'s right to object to the exhibits after he had an opportunity to review their content but also expressed Toole, Jr.'s opinion that the documents were not admissible. See **TR** 297-298 and Paper Number 89 (filed on January 18, 2002).

Based on the above-noted objections, we find there has been no waiver by Toole, Jr. Indeed, at the time the exhibits were offered there was a specific, albeit general, objection to the documents as not timely filed. Toole, Jr. also placed Vehar et al. on notice that after he had an opportunity to carefully review the documents that he reserved the right to object to the documents on other grounds. Accordingly, we shall not suppress **VX** 2967-73. The motion is denied to the extent it seeks to exclude **VX** 2967-73.

Toole, Jr.'s motion to suppress the declaration testimony of Dan EATON and Philip E. Hass is DENIED. We agree with Vehar et al. that Toole, Jr.'s failure to timely object to the manner in

which the deposition was taken, which is a condition precedent under 37 C.F.R. § 1.685(d) to filing a motion to suppress under 37 C.F.R. § 1.656(h), prohibits him from raising the issue in a motion to suppress. Moreover, we agree with Vehar et al. that the appropriate procedure for addressing the alleged irregularities during the cross examination of the witnesses would have been to phone the APJ to whom the interference was assigned for resolution of the alleged irregularities. We also here observe that the conduct complained of impacts more on the weight we shall give the testimony elicited rather than to its admissibility.

VEHAR ET AL.'S CASE FOR PRIORITY

Toole, Jr., by virtue of the filing date of his earlier filed U.S. Application Serial Number 06/725,350, is the senior party in this interference. Accordingly, Vehar et al., the junior party, bear the burden of proving priority of invention by a preponderance of the evidence. Morgan v. Hirsch, 728 F.d. 1449, 1451, 221 USPQ 193, 194 (Fed. Cir. 1984); Peeler v. Miller, 535 F.d. 647, 651, 190 USPQ 117, 120 (CCPA 1976); 37 C.F.R. § 1.657(b). A preponderance of the evidence has been defined as a standard which only requires the fact finder:

> to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence.

Boises v. Benedict, 27 F.3d 539, 541-42, 30 USPQ2d 1862, 1864 (Fed. Cir. 1994), quoting from In re Winship, 397 U.S. 358, 371-72 (1970).

Vehar et al. have alleged in their preliminary statement (see Paper Number 20) that Daniel J. Capon, Richard M. Lawn, Gordan A. Vehar, Dan L. Eaton and William I. Wood first conceived of the invention of Count 1 and Count 2 on December 13, 1983, and January 2, 1984, respectively, and that they began the active exercise of reasonable diligence towards an actual reduction to practice of the invention of the counts between December 13, 1983, and January 2, 1984. Vehar et al. have also alleged that Daniel J. Capon, Richard M. Lawn, Gordan A. Vehar, Dan L. Eaton and William I. Wood actually reduced to practice the subject matter of Counts 1 and 2 between December 13, 1983 and January 2, 1984. In their brief, Vehar et al. argue that they are entitled to an award of priority with respect to the subject matter of each count based on a theory of prior conception coupled with reasonable diligence or, alternatively, based on an actual reduction to practice of the subject matter of the counts before Toole, Jr.'s effective filing date.

Pursuant to 37 C.F.R. § 1.657(a), there is a rebuttable presumption that the inventors made their respective inventions in the chronological order of their effective filing dates.

THE COUNTS

Interpretation of a count is a question of law. Credle v. Bond, 25 F.3d 1566, 1571, 30 USPQ2d 1911, 1915 (Fed. Cir. 1994). Absent ambiguity, a count is given its broadest, reasonable interpretation without resort to either party's specification. Davis v. Loesch, F.d., 27 USPQ2d 1440, 1444 (Fed. Cir. 1993); DeGeorge v. Bernier, 768 F.d. 1318, 1321-22, 226 USPQ 758, 761 (Fed. Cir. 1985). The language of the count is given its ordinary, accustomed meaning. Johnson Worldwide Assocs. Inc. v. Zebco Corp., 175 F.3d 985, 990, 50 USPQ2d 1607, 1610 (Fed. Cir. 1999). Determination of whether an ambiguity exists requires consideration of both the language of the count and the reasonableness of the parties' arguments concerning the meaning of the count. Kroekel v. Shah, 558 F.d. 29, 31-32, 194 USPQ 544, 546 (CCPA 1977). The interpretation of the count urged by the parties in their arguments must be reasonable and not contradictory to ordinary meaning of the count. The mere fact that the parties disagree about the meaning of a term in the count does not, *per se*, raise an ambiguity as to the interpretation of the count. Fontjin v. Okamoto, 518 F.d. 610, 186 USPQ 97 (CCPA 1975).

There are two counts in this interference, the first count is directed to a recombinant DNA and the second count is directed

to an isolated and purified factor VIII protein. According to the interference rules, separate counts are directed to separate patentable inventions. 37 C.F.R. § 1.601(f), second sentence. Because DNA is ordinarily defined by a specific nucleotide sequence a count to recombinant DNA is ordinarily a count to a specific nucleotide sequence. A count to a protein is, by definition, directed to the polypeptide which forms the protein and is defined by the sequence of amino acids which form the polypeptide.

Count 1, however, does not recite any nucleotide sequence but is, instead, defined by the protein the recombinant DNA expresses as defined by its function and by the expressed protein's amino acid sequence. Count 1 requires that the recombinant DNA, when expressed ("which upon expression") results in a shortened factor VIII precursor protein ("an active procoagulant") which after further processing retains the activity of the complete factor VIII protein **and** which shortened precursor protein also has a particular amino acid sequence.

Notwithstanding the express language of Count 1, Vehar et al. argue that Count 1 does not require expression of the protein from the recombinant DNA, testing for activity of the protein expressed or the amino acid sequence of the protein which is expressed as set forth in Count 1. See Vehar et al.'s brief in

the paragraph bridging pages 4 and 5. Rather, it is Vehar et al.'s position that the language "which upon expression results in a truncated factor VIII protein which is an active procoagulant" in Count 1 simply means that if expressed the recombinant DNA is capable of expressing said protein. Vehar et al. rely on the decision in Adang v. Fischoff, 286 F.3d 1346, 62 USPQ2d 1504 (Fed. Cir. 2002) in support of their argument that Count 1 does not require expression of the protein. Vehar et al. also represent that "if Count 1 were to require that the DNA be expressed to produce a factor VIII variant, the invention of Count 1 would be merged into Count 2 ... in contravention of 37 C.F.R. § 1.601(f) ..." For reasons which follow, we do not find any of Vehar et al.'s arguments to be persuasive.

We find nothing ambiguous about the language of the counts. Although Count 1 is directed to a recombinant DNA there is no nucleotide sequence recited or required in Count 1. Accordingly, the DNA of the count is necessarily defined by remaining language of Count 1 which defines the DNA by the precursor protein[8] which the recombinant DNA expresses and also by the amino acid sequence for that protein. Thus, not only does Count 1 require that the protein expressed by the recombinant DNA of the count have a particular activity ("truncated factor VIII protein which is an

[8] See VR 760 at lines 6 through 19.

active procoagulant") but also that the protein expressed has a particular amino acid sequence.

This interpretation follows the plain words of the count, giving every word of the count its broadest, reasonable meaning. Thus, the subject matter of Count 1 requires the recombinant DNA express a truncated factor VIII protein having procoagulant activity and the truncated protein expressed must have the sequence of the amino acids as set forth in Count 1. A truncated recombinant factor VIII DNA which when expressed does not result in a protein having procoagulant properties and the specific amino acid sequence of Count 1 would not be an embodiment within Count 1.

To give Count 1 the meaning ascribed to it by Vehar et al. would be to ignore express limitations in the count. Stated another way, to interpret the count in the manner urged by Vehar et al. would render the language after the first occurrence of "DNA" in Count 1 meaningless surplusage. Vehar et al. have not cited any authority for ignoring some of the limitations of Count 1, as their arguments would require us to do, with respect to the DNA's ability to express a particular protein having a particular amino acid sequence.

Absent ambiguity, interpretation of the count is to be made without resort to either party's disclosure. Nevertheless, and

although we find no ambiguity in the language of Count 1, we also find that Vehar et al.'s disclosure supports our interpretation of Count 1. We emphasize here that we do not rely on Vehar et al.'s disclosure for the purpose of interpreting any element of the counts but simply to demonstrate the plain meaning of words which define the subject matter of the count. On page 6 of Vehar et al.'s involved application, Vehar et al. place the problem with which they were faced in the following perspective:

> The burden of proof for expression of a recombinant factor VIII would therefore rest on proof of the functional expression of what is unquestionably a factor VIII activity. Even were prior workers to show that they obtained a full or partial clone encoding all or a portion of factor VIII, the technical problems in the expression of a recombinant protein which is four time larger than any other recombinant protein expressed to date could well have proven insurmountable to workers of ordinary skill.

Vehar et al. continue on page 6 to page 7 in setting forth what they believed to represent evidence of "successful cloning and expression of human factor VIII." Specifically, Vehar et al. set forth one of four criteria of evidence of successful cloning and expression as "Expression of a functional protein ..." Thus, unless the recombinant DNA of Count 1 expresses the particular protein of the count (both its activity and amino acid sequence) and unless that protein has the particular property required by the count (procoagulant activity) a party has not obtained an embodiment within the count.

Vehar et al.'s reliance on the decision in Adang is misplaced. In Adang, both the Board below and the court on review found the language of the count to be ambiguous. Specifically, the language "said gene is expressible in said plant" was found by the court to offer "little guidance as to the form of the protein thereby produced." Adang, at 286 F.3d 1354, 62 USPQ2d 1509-10. The court found there to be confusion about whether expression of the full length gene would be the 130 kilodalton protoxin or some other form of the protein. Here, we find no ambiguity in the count and neither party has urged that the count is ambiguous. Rather, the protein which the recombinant DNA expresses is defined in terms of both its activity and amino acid sequence. To the extent Vehar et al.'s arguments may be taken as an argument that an ambiguity does exist, they have failed to follow the law on this issue and direct us to the disclosure in either party's involved application which helps resolve the meaning of the allegedly ambiguous language. Unlike Adang, here the count does not employ phrases like "capable of expression" or "expressible" but, rather, utilizes the precise phrases "which upon expression results in truncated factor VIII protein" and "wherein the recombinant DNA encodes for a protein having the amino acid sequence of ..." The "upon expression" and "encodes for a protein having" phrases give meaning to and actually define

the DNA of the count and are not directed to mere possibilities.

As for Vehar et al.'s argument that the counts would impermissibly merge if Count 1 were held to require expression of a factor VIII variant, we simply point out that Count 2 (the protein) need not be prepared recombinantly. Thus, naturally occurring factor VIII protein may be cleaved using enzymes or other means to obtain the protein of Count 2. The subject matter of Count 2 could be prepared by expressing full length factor VIII protein from full length recombinant DNA with subsequent cleavage of the full length protein. Or, the protein could be prepared by expressing the "deletion variant" DNA of Count 1. See page 6 of Vehar et al.'s brief. Thus, the counts are implicitly distinct. Additionally, Count 1 requires that the protein expressed from the recombinant DNA have a specific deletion within a particular region of the sequence, the deletion being "of at least 581 amino acids or at least 807 amino acids"[9] while the deletion of amino acids in Count 2 is not defined by any particular number of amino acids. Thus, giving the counts their broadest reasonable interpretation, the inventions defined by the separate counts are directed to "separate patentable inventions" as required by the rules.

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[9] The different number of amino acids in the deletion of Count 1 was inserted to accommodate the parties' proofs.

INVENTORSHIP

The statute, 35 U.S.C. § 111, requires that an application for patent be made by the actual inventors. Additionally, 35 U.S.C. § 116 provides that:

> "Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

As the court noted in Kimberly-Clark Corp. v. Procter & Gamble Distributing, 973 F.d. 911, 913, 23 USPQ2d 1921, 1926 (Fed. Cir. 1992), citing from Monsanto Co. v. Kamp, 269 F.Supp. 818, 824, 154 USPQ 259, 262 (D.D.C. 1967), the principle underlying joint inventorship requires:

> that each of the inventors work on the same subject matter and make some contribution to the inventive thought and to the final result.

Thus, the question of who is an inventor in an application for patent necessarily involves an inquiry into the subject matter claimed in the application and who made what contribution to which claim or claims.

In the papers declaring this interference, the named inventors of the Vehar et al. involved application were listed as the Gordon V. Vehar; Daniel J. Capon; Richard M. Lawn; William I. Wood; Cornelia M. Gorman; Daniel L. Eaton; and, Arthur D. Levinson. The filing of a duly authorized application by joint

inventors has been held to be *prima facie* evidence of joint inventorship. Van Otteren v. Haffner, 278 F.d. 738, 741, 126 USPQ 151, 154 (CCPA 1960). Thus, Gordon V. Vehar; Daniel J. Capon; Richard M. Lawn; William I. Wood; Cornelia M. Gorman; Daniel L. Eaton; and, Arthur D. Levinson are presumed to be joint inventors of the subject matter claimed in Vehar et al.'s involved application. That is, each of the named inventors of Vehar et al.'s involved application is presumed to have contributed to at least one claim in the originally filed application. 35 U.S.C. § 116.

On July 25, 1994, Vehar et al. filed their preliminary statement (Paper Number 20) in which they alleged that Gordon V. Vehar; Daniel J. Capon; Richard M. Lawn; William I. Wood; and, Daniel L. Eaton are the inventors of the subject matter of both Count 1 and Count 2. Thus, Vehar et al. have alleged by omission of Cornelia M. Gorman and Arthur D. Levinson as inventors in their preliminary statement that neither Cornelia M. Gorman nor Arthur D. Levinson, two of the named and presumptive joint inventors in Vehar et al.'s involved application, are inventors of the subject matter of Count 1 and Count 2. Additionally, at page 10 of their brief, Vehar et al. allege as a statement of fact that Capon, Lawn, Vehar, Eaton and Wood are the inventors of the subject matter defined by counts 1 and 2.

Nevertheless, a preliminary statement is not evidence but is essentially a pleading or an allegation of facts which, **if proved**, could establish the pleading party's right to an award of priority. See Dewey v. Lawton, 347 F.d. 629, 146 USPQ 187, 188 (CCPA 1965) and 37 C.F.R. § 1.629(e) (1984). See, also Revise & Caesar, "Interference Law & Practice", Volume 1, §§ 86, 98 (1940). Toole, Jr. has correctly observed in his brief at pages 109, 110, that Vehar et al. has chosen not to file in this proceeding a motion pursuant to 37 C.F.R. §§ 1.634 and 1.636(c) to correct the inventorship of their involved application. The record also shows Vehar et al. did not file an amendment in their involved application under 37 C.F.R. § 1.48(b) while the prosecution remained open before the examiner. Thus, we presume the inventorship named in Vehar et al.'s involved application is correct.

Nevertheless, as correctly noted by Vehar et al. in their brief, it is possible for less than all the named and presumptive joint inventors of the subject matter claimed in Vehar et al.'s involved application to be the inventors of the subject matter of either or both counts. See 35 U.S.C. § 116, first paragraph, second sentence. As the party raising this issue, Vehar et al. bear the burden of proving by a preponderance of the evidence exactly who are the inventors of the subject matter of the

counts. It is not sufficient to make an allegation in the preliminary statement and rely solely on that allegation as proof of inventorship. Except for the allegation in their preliminary statement and the terse discussion of inventorship in their reply brief, Vehar et al. have virtually ignored this critical legal question in their briefs and their proofs of priority. To the extent the issue has been addressed by the parties, we must make the underlying factual inquiries necessary to reach the legal question of who are the inventors of the subject matter of the counts.

In the papers declaring this interference, all of the remaining claims pending in Vehar et al.'s involved application were designated as corresponding to either Count 1 or Count 2. Thus, we must presume that the named inventors of Vehar et al.'s involved application, which are the inventors listed in the papers declaring this interference, including Cornelia M. Gorman and Arthur D. Levinson, are the actual joint inventors of the subject matter of at least one of Vehar et al.'s pending claims in Vehar et al.'s application designated as corresponding to the counts. Accordingly, because Vehar et al. have alleged both in their preliminary statement and their brief an inventive entity different from the named and *prima facie* actual joint inventors of Vehar et al.'s involved application, as part of their priority

case Vehar et al. must prove by a preponderance of the evidence the joint inventorship as alleged in their preliminary statement.

Inventorship is a question of law. Sewall v. Walters, 21 F.3d 411, 415, 30 USPQ2d 1356, 1358 (Fed. Cir. 1994). However, the legal determination of inventorship is based on the underlying facts which support the legal conclusion. Hess v. Advanced Cardiovascular Sys., Inc., 106 F.3d 976, 980, 41 USPQ2d 1782, 1785-86 (Fed. Cir. 1997). It has been consistently held that "[c]onception is the touchstone to determining inventorship." Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Conception has been held to be "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention as it is hereafter to be applied in practice." Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.d. 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986). Ethicon Inc. v. United States Surgical Corp., 135 F.3d 1456, 1460, 45 USPQ2d 1545, 1548 (Fed. Cir. 1998).

While the rules permitting a change in inventorship are remedial in nature and, ordinarily, would be liberally construed, in an *inter partes* context, who is an inventor and who is not an inventor is extremely relevant to the proceeding because who is an inventor bears on who can or cannot corroborate evidence of conception and actual reductions to practice. As observed by

Judge Newman speaking for the court in their decision in Stark v. Advanced Magnetics Inc., 29 F.3d 1570, 1575, 31 USPQ2d 1290, 1294 (Fed. Cir. 1994):

> Indeed, we agree that diligent action is required during a pending interference proceeding, where a change of inventorship can directly affect the trial and outcome of the proceeding. Such a requirement is guided by the principles governing the duties of parties litigant. *See* Van Otteren v. Hafner, 278 F.d. 738, 126 USPQ 151 (CCPA 1960) ...

Accordingly, if each of named and presumed joint inventors of Vehar et al.'s involved application did not contribute to the subject matter of any of the claims remaining in the application when this interference was declared, it was incumbent upon Vehar et al. to have either filed a petition under 37 C.F.R. § 1.48(b) while prosecution of the application was open or a motion under 37 C.F.R. § 1.634 after the interference was declared.[10] Vehar et al. failed to take either action.

Furthermore, because the filing of a duly executed joint application is *prima facie* evidence of joint inventorship, it is Vehar et al.'s burden to establish by a preponderance of the evidence that the other originally named and presumed joint inventors, Gorman and Levinson, are not joint inventors of the subject matter of either Count 1 or Count 2. See, Coleman v.

[10] Both the petition under §1.48(b) and the motion under §1.634 are directed to who is an inventor of what is claimed in an application **not** who are the inventors of the subject matter a count in an interference.

Dines, 754 F.d. at 357, 224 USPQ at 860 concerning conclusory averments in statements made in furtherance of a change in inventorship.

The only discussion of inventorship in Vehar et al.'s brief is in the statement of facts where we find the inventors of the invention of the counts set forth under the heading "GENENTECH'S FACTOR VIII TEAM." Vehar et al.'s main brief at page 10. Therein 5 (five) of the 7 (seven) named and presumed joint inventors of Vehar et al.'s involved application are named as "inventors of the inventions defined by Counts 1 and 2 of this Interference." At page 16 of Vehar et al.'s main brief, Dr. Gorman is described as one member of the factor VIII team who carried out research in one of a variety of different disciplines in a variety of different departments. On page 17 of Vehar et al.'s main brief, Dr. Gorman[11] is described as working in the cell culture discipline.

During her cross examination, Dr. Gorman was asked if she believed herself to be an inventor of the subject matter originally claimed in Vehar et al.'s involved application. Dr. Gorman candidly answered that she did not know from a legal standpoint what constitutes inventorship. **VR** 1311-13; 1317; 1318, lines 18 through 20. Dr. Gorman also testified that, based on her

[11] We presume "Cori" Gorman is Dr. Cornelia Gorman.

understanding of inventorship as requiring a "contribution" to the subject matter in the application, she had "contributed" and, therefore, believed herself to be an inventor of at least some of the claims in the involved Vehar et al. application. **VR** 1313 at lines 1 through 20. Dr. Gorman also testified that she "had no role in actually conceiving the idea of making factor **VIII** variants." **VR** 1317, lines 2 through 4. Dr. Gorman testified that she did not consider herself to be an inventor of the subject matter of claims 50 or 51. **VR** 1333, lines 3 through 11. Claim 51 is a claim designated as corresponding to Count 1. While Dr. Gorman testified that she did not "contribute" to virtually any of original claims 1 through 37 in the involved Vehar et al. application, Dr. Gorman testified that she at least "contributed" to the subject matter of Claims 38 through 46. **VR** 1333, line 19 through **VR** 1335, line 24. Claim 38 is designated as corresponding to Count 1.

As correctly observed by Vehar et al.'s lead attorney during the cross examination of Dr. Gorman, "questions of inventorship are clearly difficult for a ... for a non-lawyer." **VR** 1320. Thus, Dr. Gorman's understanding of what constitutes the legal question of inventorship is not controlling or even, necessarily, relevant to the issue before us. We must weigh all the underlying facts presented and determine if Vehar et al. have proved that it is

more likely than not that the alleged inventors of the subject matter of the count are Vehar, Capon, Lawn, Wood and Eaton.

Dr. Gorman's testimony is, at best, equivocal on this matter. On the one hand, she believes she "contributed" to at least some of the original claims and specifically to at least claims 38 through 46. On the other hand, Dr. Gorman stated her belief that she did not "contribute" to any of claims 1 through 37 of Vehar et al.'s involved application. However, our inquiry does not end with Dr. Gorman and we do not credit her testimony on the issue of inventorship based on her unexplained understanding of the legal issue of what constitutes inventorship. Glaring by its absence from the record is any testimony by Arthur D. Levinson, one of the named and presumptive joint inventors of Vehar et al.'s involved application, concerning what was his "contribution" to the claims designated as corresponding to the count. Also absent in the record is any evidence indicating that Vehar et al.'s legal counsel pursued the issue of inventorship beyond the mere allegations in the preliminary statement or, if pursued, how it was determined for purposes of filing the preliminary statement that Gorman and Levinson were **not** inventors of the subject matter of any claim designated as corresponding to the count.

On balance, considering Dr. Gorman's testimony most favorably to Vehar et al., we find that Vehar et al. have failed to provide sufficient evidence which overcomes the presumption that the originally named inventors are also the inventors of the subject matter of the counts. Accordingly, we find that the named and presumed joint inventors of the Vehar et al. involved application, including Dr. Gorman and Arthur D. Levinson, are inventors of the subject matter of the counts. Accordingly, Dr. Gorman's testimony must be corroborated and Dr. Gorman's testimony may **not** be relied on for corroboration of any other inventor's testimony.

VEHAR ET AL.'S CASE FOR PRIOR CONCEPTION

According to Vehar et al.'s brief, on July 30, 1984, Dr. Wood, one of the named inventors, prepared a written outline (**VX** 135) describing the subject matter of Count 1. See also Dr. Wood's declaration testimony (**VR** 363-66). The subject matter discussed in Dr. Wood's outline became known as the "90/80 fusion" in the Genentech factor VIII team based on the proposed fusion of a 90 kilodalton segment of nucleotides comprising part of the full length factor VIII DNA with an 80 kilodalton segment of nucleotides comprising part of the full length factor VIII DNA, each segment remaining after part of the DNA which encodes the B domain of factor VIII protein was cut out with restriction

enzymes and the remaining segments fused. Vehar et al. urge that Dr. Wood's outline serves as a conception of the subject matter of both counts. See Vehar et al.'s brief at page 102. Nevertheless, the "Wood outline" is a handwritten document, described in terms of various unexplained acronyms which are not self-explanatory.

Philip Hollingshead, an employee of Genentech who reported to Dr. Wood (**VR** 75, 103), is offered as a corroborator of the alleged conception as represented by Dr. Wood's outline based on his (Hollingshead's) discussion of Dr. Wood's outline with Dr. Wood on the day following creation of the outline, that is, July 31, 1984 (**VR** 78). In 2001, Hollingshead has testified that Dr. Wood's outline conveyed to him (Hollingshead) in 1984, the preparation of a plasmid[12] coding for a variant of factor VIII protein wherein the DNA coding for a portion of the B domain would be deleted and the remaining portions fused together to yield a recombinant DNA coding for a "truncated" factor VIII protein. **VR** 78. Subsequently, on August 14, 1984, Hollingshead prepared a plasmid (**pAML3P.8c19**) including the "90/80 fusion." (**VR** 78-86; 367). Hollingshead subsequently ran experiments

[12] "A *plasmid* is a small circular loop of DNA that can be introduced into bacteria and will then replicate itself as the bacterial cells grow and divide." In re O'Farrell, 853 F.d. at 898, 7 USPQ2d at 1677.

(Northern and Southern blots) to detect the presence of **RNA** and **mRNA** from cells transfected with the "90/80 fusion" plasmid (**VR** 382). The work performed by Hollingshead allegedly confirmed that **mRNA** had been successfully transcribed from the "90/80 fusion" transfected cells (**VX** 373-74). Dr. Wood's October 18, 1984, summary of the Northern and Southern blots performed by Hollingshead is allegedly corroborated by Hollingshead and Dr. Gorman (**VR** 86-90; 380-382; 1642-1643).

On December 3, 1984, Hollingshead began to construct another different plasmid (**pAML3P.8cNDV**) containing the same "90/80 fusion" which had previously been determined to yield **RNA** and **mRNA** (**VR** 95-96). On December 12, 1984, cells were transfected with the newly constructed plasmid (**VR** 171). On December 31, 1984, Lisa Comstock allegedly tested a protein expressed from the transformed cells for protein activity (**VR** 192-200) and she generated a printout of the assay she obtained for the samples she tested (**VX** 341; **VR** 1609). On January 3, 1985, Lisa Comstock allegedly selected 6 of the 12 clones she assayed on December 31, 1984, based on their high optical density readings for "confirmatory reassay." Dr. Gorman explained the results of Lisa Comstock's "reassay" (**VR** 1637-38). Thus, Vehar et al. allege that the determination by Lisa Comstock that the samples she tested on

December 31, 1984, had activity indicative of a factor VIII protein was an actual reduction to practice of the subject matter of Count 1. Vehar et al. allege the actual reduction to practice was corroborated by Comstock's notebook, Dr. Gorman's testimony, Dr. Gorman's notebook and Philip Hollingshead's testimony. See Vehar et al.'s main brief at pages 84 and 85 and pages 107 and 108.

According to Vehar et al.'s brief, the so-called "Wood outline" (**VX** 135) is sufficient evidence of conception of both the subject matter of Count 1 and Count 2. Dr. Lawn, one of the named inventors of Vehar et al.'s involved application, has testified that according to Dr. Wood's outline:

> deletion of 766 amino acids within the region between 796 and 1563 of the B domain of factor VIII DNA coding sequence would be made by fusing the **Tth**1111 site at amino acid 796 to the **Bam**HI site at amino acid 1563 after filling both sites with DNA polymerase I.[13]

and serves as evidence that the "90/80" fusion would result in the DNA of Count 1. **VR** 10, lines 3 through 6. Nevertheless, the basis for Dr. Lawn's testimony in 2001 is not apparent from the "Wood outline" itself prepared in 1984. Clearly, nothing on the outline itself mentions any protein let alone particular amino acids in any protein. Rather, "Part A" of the "Wood outline"

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[13] Dr. Vehar's, Dr. Capon's and Dr. Eaton's testimony uses the identical language to summarize the content of the "Wood outline." See **VR** 44; 70-71; and 247.

defines two different procedures for preparing what appear to be two different DNA constructs using what appear to be two different plasmids and the restriction enzymes used to cut the plasmids at certain nucleotides. Vehar et al. have presented no evidence which establishes that in 1984 a person of ordinary skill in this art would have read the outline and understood it to describe the subject matter of Count 1 or Count 2.

Although each of the inventors has testified in 2001 about what the "Wood outline" meant to them in 1984, we have not been directed to any contemporaneous-in-time evidence which supports any of the inventors' testimony. While numerous witnesses have also alluded to the extensive meetings held by the "factor VIII team" in the time period from 1984 through 1986 concerning the team's research efforts in the relevant time period, glaring by its absence from the record is any evidence of any meeting actually held, including what topic was allegedly discussed or what work being carried out was reviewed in said meetings. There are no memoranda, progress reports, e-mails or even handwritten notes from any meetings of the factor VIII team. More significantly, Dr. Lawn's testimony (and, thus, Dr.'s Vehar, Capon and Eaton's testimony) on this matter is, at best, confusing. Dr. Lawn speaks in terms of deleting amino acids from "the B domain of factor VIII DNA coding sequence." As we

observed during the presentation of Vehar et al.'s oral argument, DNA is described by nucleotides, not amino acids and proteins are described in terms of amino acids not nucleotides. See Paper Number 141, page 12, line 19 through page 14, line 2. Nothing in the "Wood outline" can be construed as connoting that it was intended by the outline to delete a particular section of nucleotides (the nucleotides which encode the B domain in factor VIII protein) from the full length factor VIII DNA, reconnect certain remaining fragments of the full length DNA obtained to achieve a new, shortened DNA which when expressed yielded a procoagulant protein having an amino acid sequence as set forth in Count 1.

The "Wood outline" (**VX** 135, 136) does not set forth any discussion of either proteins or the deletion of amino acids but is directed to the preparation of recombinant DNA by fusion of pieces of DNA obtained from two, different plasmids without reference to <u>any</u> amino acids. The two plasmids, identified as **pAML3P.8c1** (**VX** 20A and 20B) and **pAML3P.8c9** (**VX** 28A and 28B), are plasmid numbers 29 and 53, respectively, in the "Genentech Master Plasmid Notebook." **VR** 364-365. Nothing in either of the notebook entries for these plasmids identifies where in the full length factor VIII DNA the nucleotides which encode for the B domain of the factor VIII protein may be found in either plasmid. Thus, the

basis for Vehar et al.'s conclusion that the "Wood outline" was directed to recombinant DNA formed by joining the DNA segments remaining after the deletion of the corresponding nucleotides which encode for part of the B domain of full length factor VIII protein is not apparent from the very documents on which Vehar et al. rely.

While Dr. Wood's testimony makes repeated reference to the deletion of certain amino acids within the region between amino acid 796 and 1563 of the B domain of factor VIII DNA coding sequence, nothing in the "Wood outline" speaks in terms of any protein let alone an amino acid sequence of any protein. All the references in **VX** 135 and 136 are to nucleotide base pairs not amino acids. See **VR** 365-66. Dr. Lawn's further testimony confirms that the "Wood outline" discusses nucleotides not amino acids. See **VR** 12-13. Thus, there is no factual basis in the "Wood outline" itself or any of the testimony in this record for Dr. Wood's conclusions in 2001 about the amino acid sequence of the protein which the "90/80" DNA fusion construct might encode in 1984.[14] Finally, as inventors, Dr. Wood's, Dr. Lawn's, Dr.

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[14] "Even after a cloned heterologous gene has been successfully inserted into bacteria using a plasmid as a cloning vector, and replicates as the bacteria grow, there is no guarantee that the gene will be expressed, i.e., transcribed and translated into protein. ... The genetic engineer needs a method to "turn on" the cloned gene and force it to be expressed." O'Farrell, 853 F.d. at 899, 7 USPQ2d at 1677.

Vehar's, Dr. Capon's and Dr. Gorman's testimony requires corroboration. We have not been directed to what evidence or testimony corroborates their testimony. Lisa Comstock's notebooks and the associated testimony directed to those notebooks has been excluded from the evidence and, therefore, may not be relied on to prove Vehar et al.'s priority case.

We have not overlooked Dr. Villa-Komaroff's opinions on this matter but, even assuming she is an expert, even the opinion of an expert must find an underlying basis in the evidence.[15] The basis for Dr. Villa-Komaroff's opinions are not apparent from the record nor has she stated exactly what formed the basis for her opinions as set forth in paragraphs 4 through 7 of her affidavit. See **VR** 225. Further, we have not been presented with any evidence from Dr. Villa-Komaroff in the relevant time frame, that is, 1984 evidencing her understanding at that time of what the "Wood outline" described. Accordingly, we do not give her opinions significant weight.

Vehar et al. urge that because both parties "agree" that conception of the subject matter of both counts may be proven by outlines setting forth restriction enzyme maps including the cleavage sites to be cut within the **B** domain coding region of

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[15] Cable Electric Products, Inc. v. Genmark, Inc., 770 F.d. 1015, 1025, 226 USPQ 881, 887 (Fed. Cir. 1985); In re Grunwell, 609 F.d. 486, 491, 203 USPQ 1055, 1059 (CCPA 1979). **FRE** 702(1).

full length factor VIII DNA to obtain the individual DNA segments to be rejoined we must accept the "Wood outline" as evidence of prior conception. Vehar et al. also argue that the techniques used to prepare the DNA construct of Count 1 from the segments of the B domain coding region of full length factor VIII obtained using various restriction enzymes was "relatively straightforward" so the "Wood outline" is sufficient evidence of a complete conception of the subject matter of Count 1. The basis for this conclusion is, apparently, the alleged obtention by Hollingshead within about two weeks after the date of the "Wood outline" of a construct prepared according to the outline.

Hollingshead, however, never expressed a protein from any construct he prepared and Hollingshead testified that he did virtually no work with proteins. VR 90; 1412. Count 1 requires that the recombinant DNA express a protein with a particular activity and a protein having a particular amino acid sequence. Hollingshead also testified that his early attempts at preparing a plasmid according to Dr. Wood's outline failed. VR 82. His confirmatory work ultimately establishing that the constructs he prepared were producing RNA and mRNA does not establish translation of the RNA into a polypeptide, that is, a protein let alone a protein having "procoagulant activity" and the amino acid sequence of Count 1. Hollingshead also testified that at the

time the constructs were prepared "the science was rather new, and so we were trying different promoters, different enhancer elements and that sort of thing ." VR 1436.

Further, in 1984 when the work was actually performed, there was no reasonable expectation that the gene would be expressed, that is, transcribed and translated into a protein. As Dr. Gorman testified concerning Hollingshead's efforts to prepare a construct including the "90/80" fusion:

> I had further conversations with Bill Wood about the data as far as knowing that the RNA came from the same vector that was used in the experiments for the transfection and we see the data from the assay that Lisa ran on December 31st. So we knew that the vector which had been shown to make the full-length protein made RNA that was specific to the 90/80 fusion as well. **All that was left was to look for the protein**. (emphasis ours)

VR 1642-1643. Dr. Lawn's testimony on this matter is consistent with the fact that, in 1984 when the work was performed, successfully obtaining protein from recombinant DNA could not be reasonably predicted or even expected. Thus, Dr. Lawn testified:

> Well, I think that -- that it may have been suggestive of a hypothesis that would have required testing, as we did. And of course, the exact location, the exact termini of these fragments could not have been known at this time. But it -- it suggested a hypothesis to us, and it may have suggested a hypothesis to others, to -- to subsequently test.

VR 764-765. In further response to the question "was it obvious that the construct would have factor VIII activity?", Dr. Lawn responded:

> No, it was a plan to test that. It was a plan to test that hypothesis. We thought it probably would. But it was a research hypothesis.

VR 766. Finally, with respect to the plasmid **pAML3P.8c19**, Dr. Lawn testified that he was unaware of any experiment which demonstrated that a cell transfected with **pAML3P.8c19** showed "activity." See **VR** 770, lines 21 through 24. See also **VR** 774, line 18 through 775, line 14; **VR** 903, lines 7 through 9 and lines 22 through 25; **VR** 904, lines 1 through 7.

The question of whether Vehar et al. have proved a conception of the subject matter of Count 1 is rendered even more difficult by the passage of time. More than 19 (nineteen) years have passed since the events alleged in Vehar et al.'s brief took place. We must consider the evidence in the light it would have been considered in 1984 through the eyes of the skilled routineer in 1984. We must also exercise great caution against considering the events of 1984 through the prism of current knowledge in the art. Although neither party has honored the record with evidence showing what was the state of the art in the relevant time frame, we find that it is clear from all the discussion above that in 1984, when the alleged work was performed, the results obtained would have been entirely unpredictable. Thus, Vehar et al.'s proofs, at best, establish that Vehar et al. had a research objective to make a recombinant DNA, a plasmid, as represented by

the "Wood outline", but the "Wood outline" does not describe or define a conception of the subject matter of Count 1. The decisions of our reviewing court in In re O'Farrell, *Id.* and Amgen, Inc v. Chugai Pharmaceutical Co. Ltd., 927 F.d. 1200, 18 USQP2d 1016 (Fed. Cir. 1991) are consistent with the fact that recombinant technology was in its infancy in the time frame of 1984-85. In O'Farrell, the application in issue had been filed in August 1980 but was a division of an application filed in 1978. In Amgen, the patents in issue were filed in November 1984 and January 1985, respectively. Thus, the court's observations concerning the state of the art in that time period is relevant to the issue before us here.

That the parties may agree that conception of the counts in this interference may be "established with an outline demonstrating the enzyme cleavage sites to be cut within the region of the factor VIII B domain" is not binding on this Board. The question to be resolved here is: do the junior party's proofs establish conception of the subject matter of the counts? Count 1 is not directed to any recombinant DNA but to a particular recombinant DNA which when expressed yields a protein having a particular activity and a particular amino acid sequence. We find no evidence in the record which establishes that the expression of proteins from DNA was so predictable in 1984 when Vehar et

al.'s research was undertaken that simply envisioning the preparation of a DNA molecule which may or may not, when expressed, yield a particular protein was tantamount to obtaining a protein therefrom. Simply stated, without evidence proving that the DNA envisioned would express a protein from the recombinant DNA having procoagulant activity, that is, activity obtained when the protein expressed underwent further processing and without knowing that the amino acid sequence of the protein expressed would be the amino acid sequence required by Count 1, we do not find Dr. Wood's outline to be evidence of conception of the subject matter of Count 1.

Vehar et al. also argue that both parties believed that because the B domain of full length factor VIII protein was cleaved out of the protein during processing in humans and was therefore structurally unnecessary for activity, it was reasonable to expect that the corresponding nucleotides in full length DNA for factor VIII protein encoding for the B domain could also be deleted and yet the protein obtained by expression of said DNA would still retain the full length factor VIII protein's activity. The basis for Vehar et al.'s belief is alleged to be, in part, an article published in Nature in 1984 by the Vehar et al. inventors and others which allegedly recognized the "homology" between factor V and factor VIII (**VX** 342-347).

However, the article published in Nature in 1984 (VR 362) on which Vehar et al. rely does not stand for that proposition. Rather, the article speaks in terms of possibilities ("Both subunits are required for factor V activity and both may be required for factor VIII activity." - emphasis ours; "Therefore, both factors V and VIII seem to be highly similar in structure, thrombin cleavage pattern and, presumably, function." - emphasis ours). Only after preparing the recombinant DNA, inserting it in a vector and transforming a cell which ultimately expresses the protein and then determining the activity and the sequence of the protein may the possibilities alluded to in the article in Nature be tested.

Thus, whether based on the fact that their conception was incomplete, that is, that their proof of conception lacked any evidence that Vehar et al. knew or recognized how to obtain the protein having the procoagulant activity and amino acid sequence required by Count 1 in 1984 or whether the subject matter of both counts was in 1984 only capable of being conceived simultaneously at the time it was actually reduced to practice[16], Vehar et al.

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[16] Smith v. Bousquet, 111 F.d. 157, 162, 45 USPQ 347, 352 (CCPA 1940); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.d. 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991); Burroughs Wellcome Co. v. Barr Laboratories Inc., 40 F.3d 1223, 1228-29, 32 USPQ2d 1915, 1920 (Fed. Cir. 1994) ("a conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's ideas that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice.")

have failed to prove a conception or an actual reduction to practice of the subject matter of the counts. Vehar et al. have failed to direct our attention to the evidence in the record which establishes that they had obtained a protein having the requisite activity (an active procoagulant) and the amino acid sequence required by Count 1 from the DNA in any of the plasmids they prepared or a protein having the amino acid sequence of Count 2 at a time prior to Toole, Jr.'s effective filing date.

Vehar et al. make repeated reference to the relationship between their work on the full length recombinant DNA encoding factor VIII protein and the subject matter of the counts, that is, deletion variants of the recombinant full length DNA and deletion variants of factor VIII protein, as one basis for finding the "Wood outline" to be sufficient evidence of conception of the subject matter of the counts. Suffice it to say that while the two are related, the full length recombinant DNA encoding factor VIII protein and the subject matter of the counts in this proceeding are, by definition, separately patentable inventions. Further, and contrary to Vehar et al.'s representations that in 1984 when the research was conducted recombinant technology was so predictable that the idea for preparing the "90/80" fusion was a conception of the subject matter of Count 1 and Count 2, we find that there is absolutely

no evidence in the record which supports Vehar et al.'s naked allegation.

Because we have found Vehar et al.'s proofs of conception to be inadequate to meet their burden of persuasion for both Count 1 and Count 2, we need not address Vehar et al.'s evidence of reasonable diligence. Absent evidence of prior conception, Vehar et al.'s theory of conception plus reasonable diligence which they believe entitles them to an award of priority also fails.

VEHAR ET AL.'S ACTUAL REDUCTION TO PRACTICE

The facts on which Vehar et al. rely to prove an actual reduction to practice of the subject matter of Count 1 are set forth on pages 28 through 46 of their main brief. Therein, as part of their case-in-chief, Vehar et al. rely on the testimony of Dr. Villa-Komaroff for their interpretation of Count 1 as not requiring expression of or, therefore, amino acid sequencing, of the protein expressed by the recombinant DNA. See Vehar et al.'s brief at pages 45 and 46; VR 855, lines 9 through 19. According to their brief, the subject matter of Count 1 was reduced to practice on October 14, 1984, when Dr. Wood prepared a summary of the RNA experiments performed by Hollingshead. Vehar et al. brief at pages 32-33.

The facts on which Vehar et al. rely to prove an actual reduction to practice of the subject matter of Count 2 are set

forth in Vehar et al.'s brief at pages 47 through 86. According to their brief, the subject matter of Count 2 was actually reduced to practice on December 31, 1984, when Lisa Comstock tested a sample produced from **BHK** cells transfected using a "90/80" fusion DNA as described in the "Wood outline" and found the sample had sample tested positive for "procoagulant activity."

COUNT 1

According to Vehar et al., when the first constructs prepared by Hollingshead (plasmid **pAML3P.8c19**) were successfully transfected in **CHO** cells and both **RNA** and **mRNA** positively detected in those transfected cells, Vehar et al. had reduced to practice the subject matter of Count 1 at a time when Toole, Jr. had at best only conceived of the subject matter of the counts. Nevertheless, this argument is founded on Vehar et al.'s interpretation of Count 1 as not requiring either actual expression of a truncated, procoagulant protein from the recombinant DNA prepared by Hollingshead or amino acid sequencing of the expressed, truncated procoagulant protein. As we have found above, we do not find Vehar et al.'s interpretation of Count 1 to be the broadest, reasonable interpretation of Count 1. To give Count 1 the meaning ascribed to it by Vehar et al. would be to ignore both the limitation that the recombinant DNA "upon

expression results in truncated factor VIII protein which is an active procoagulant" and also the limitation that the DNA "encodes for a protein having the amino acid sequence of a human factor VIII:C except for having a deletion corresponding to ..." If those two limitations are read out of Count 1 then Count 1 would simply become a count to an otherwise uncharacterized recombinant DNA! The law concerning interpretation of counts requires that every limitation in the count be given its broadest, reasonable interpretation and to prove an actual reduction to practice of a count an embodiment including every limitation of the count must have actually been made and performed as intended (shown to have utility). Schendel v. Curtis, 83 F.3d 1399, 1402, 38 USPQ2d 1743, 1746 (Fed. Cir. 1996); Newkirk v. Lulejan, 825 F.d. 1028, 1032, 3 USPQ2d 1793, 1794 (Fed. Cir. 1987). Thus, Vehar et al. were required to prove that they had prepared a recombinant DNA meeting every limitation of Count 1.

Based on their interpretation of Count 1, Vehar et al. argue that Hollingshead's "successful construction of a plasmid containing the DNA sequence for B domain deletion factor VIII" in August 1984 was an actual reduction to practice of an embodiment within Count 1. That alleged actual reduction to practice was "confirmed" when Dr. Wood prepared his October summaries of

Hollingshead's experiments. However, even accepting that Hollingshead had successfully prepared a plasmid including the less-than-full-length recombinant factor VIII DNA which encodes for a truncated procoagulant protein, until a protein was successfully expressed from the plasmid and sequenced there could be no actual reduction to practice of the subject matter of Count 1. As we have observed above, even when a plasmid is found to express **RNA** and **mRNA**, both necessary precursors to the expression of a protein, it does not necessarily follow that expression of any protein takes place. Thus, assuming, *arguendo*, that Vehar et al. may have, indeed, prepared a recombinant DNA which expressed both **RNA** and **mRNA**, it remains to be answered what DNA was prepared and whether that DNA would express the protein of Count 1 as defined by its specific amino acid sequence. Certainly, it is not apparent from Dr. Wood's notebook (**VX** 373) or Dr. Wood's testimony explaining the entries in said notebook (**VR** 382) that the DNA Hollingshead prepared, when expressed, would yield a truncated procoagulant factor VIII protein having less than the full amino acid sequence of full length factor VIII protein.

Further, while Vehar et al. make continued reference to their determination that the **mRNA** "was consistent with the proper size and sequence for the production of B domain deletion factor VIII protein", we have not been directed to what evidence in the

record establishes in 1984 exactly what was considered to be the "proper size and sequence" of the less than full length recombinant DNA which encodes for the truncated factor VIII protein having procoagulant activity. Indeed, there is virtually no reference in any of Vehar et al.'s evidence to what they believed was the portion of the full length DNA for factor VIII which was responsible for and necessary for the expression of the truncated protein. Stated another way, it is not clear from the record nor have Vehar et al. adequately explained what in the record forms the basis for their conclusion that the plasmid **pAML3P.8c19** "was made by excising the DNA encoding for amino acids 797-1562 of the B domain" (Vehar et al.'s brief at page 45) or that the plasmid containing the "90/80" fusion DNA was "consistent with a size and sequence of DNA that upon expression results in truncated factor VIII proteins" (Vehar et al.'s brief at page 106).

Vehar et al.'s reliance on Dr. Gorman's testimony for purposes of corroboration is poorly taken. As we have stated above under the heading "INVENTORSHIP", Vehar et al. have failed to prove by a preponderance of the evidence that the named joint and presumed actual inventors of the involved Vehar et al. application are not the inventors of the subject matter of the counts. Accordingly, Dr. Gorman is an inventor and her testimony

may not be relied upon to corroborate any inventor's testimony. Indeed, as an inventor, her testimony requires corroboration!

Simply stated, Vehar et al. have failed to prove that any recombinant DNA prepared by them in 1984 before the effective filing date of the senior party expressed a truncated protein having procoagulant activity (that is, a shortened form of full length factor VIII protein) and that the protein expressed had an amino acid sequence with the deletion in its sequence required by Count 1. There being no proof of such recombinant DNA, Vehar et al. have failed to meet their burden of proof for an actual reduction to practice of the subject matter of Count 1.

COUNT 2

Vehar et al. also argue that Hollingshead's successful construction of a second plasmid (**pAML3P.8c19NDV**) and its use to successfully transfect **BHK** cells to express an active protein constitutes an actual reduction to practice of the subject matter of Count 2. See Vehar et al.'s brief at page 108.

Toole, Jr. urge that because Vehar et al. never successfully expressed from either plasmid a protein with a B domain deletion which still exhibited procoagulant activity that neither plasmid constructed by Hollingshead or the proteins prepared from said constructs can be relied on as an actual reduction to practice of the subject matter of either count. Toole, Jr. brief at page 17.

According to Toole, Jr., there was a sequencing error in Hollingshead's August 1984 plasmid construct which required Hollingshead to prepare another construct in November 1984. See Toole, Jr.'s brief at pages 14 and 15. Toole, Jr. also urge that there is no evidence that the second plasmid construct was ever successfully used to transfect cells and express active protein.

Vehar et al. rely on Dr. Gorman's testimony that on December 12, 1984, **BHK** cells had been transfected with the "90/80" fusion DNA in plasmid **pAML3P.8c19NDV**. According to Vehar et al., on December 31, 1984, Lisa Comstock tested the protein allegedly produced from the transfected **BHK** cells and reported "positive Factor VIII activity." Vehar et al.'s brief at page 57. But Dr. Gorman's testimony and Vehar et al.'s proofs rely on the alleged work of Lisa Comstock as represented by her laboratory notebooks which notebooks have been excluded from the evidence. Thus, Vehar et al. have not presented any evidence of the construction of an embodiment within Count 2 or evidence that an embodiment within Count 2 was ever adequately tested for utility. Accordingly, we do not credit Vehar et al. with having proved an actual reduction to practice of the subject matter of Count 2 by December 31, 1984.

In reaching our conclusion we have not overlooked Vehar et al.'s arguments that the inventors, as evidenced by their

testimony, appreciated and understood Lisa Comstock's experiments. Nevertheless, these arguments, like Dr. Gorman's testimony, rely on evidence which has been excluded. Further, as the testimony relied on is that of the inventors, all the testimony also requires corroboration. The only non-inventor to whose testimony we have been directed for purposes of corroboration is Hollingshead's and that testimony is directed exclusively to evidence which has been excluded. Because Vehar et al. have not directed our attention to any other evidence of an actual reduction to practice, we find Vehar et al. have failed to meet their burden of persuasion and proven that they actually reduced to practice an embodiment within the scope of Count 2 before Toole, Jr.'s effective filing date.

JUDGMENT

Having decided all the issues properly raised before us, it is now appropriate for us to render final judgment in this interference. Accordingly, pursuant to our authority under 37 C.F.R. § 1.658(a) and in view of our holding that Vehar et al. have failed to meet their burden of persuasion, we enter the following judgment.

Judgment as to the subject matter of Count 1 in this interference is entered against Gordon V. Vehar, Daniel J. Capon, Richard M. Lawn, William I. Wood, Cornelia M. Gorman, Daniel L.

Eaton, and Arthur D. Levinson, the junior party. Gordon V. Vehar, Daniel J. Capon, Richard M. Lawn, William I. Wood, Cornelia M. Gorman, Daniel L. Eaton and Arthur D. Levinson, the junior party, are not entitled to a patent containing claims 38, 41 and 51 through 53 of their involved application Serial Number 07/584,076 and designated as corresponding to Count 1.

Judgment as to the subject matter of Count 1 is awarded to John J. Toole, Jr., the senior party. On this record, as the first inventor of the subject matter of Count 1, John J. Toole, Jr. is entitled to his patent containing claims 1 through 9 of his involved patent U.S. Patent Number 4,868,112 and designated as corresponding to Count 1.

Judgment as to the subject matter of Count 2 in this interference is entered against Gordon V. Vehar, Daniel J. Capon, Richard M. Lawn, William I. Wood, Cornelia M. Gorman, Daniel L. Eaton, and Arthur D. Levinson, the junior party. Gordon V. Vehar, Daniel J. Capon, Richard M. Lawn, William I. Wood, Cornelia M. Gorman, Daniel L. Eaton and Arthur D. Levinson, the junior party, are not entitled to a patent containing claims 22 through 30, 47, 54 and 55 of their involved application Serial Number 07/584,076 and designated as corresponding to Count 2.

Judgment as to the subject matter of Count 2 is awarded to John J. Toole, Jr., the senior party. On this record, as the

first inventor of the subject matter of Count 2, John J. Toole, Jr. is entitled to his patent containing claims 10 and 11 of his involved patent U.S. Patent Number 4,868,112 and designated as corresponding to Count 2.

MARC L. CAROFF)
Administrative Patent Judge)
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ANDREW H. METZ)BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
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U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

INTERFERENCE DIGEST

Interference No. 103215 Paper No. 14

Name, John J. Toole, Jr.

Serial No. 07/010,085 Patent No. 4,868,112, issued 09/19/89

Title, NOVEL PROCOAGULANT PROTEINS

Filed, 04/11/86

Interference with Vehar et al.

DECISION ON MOTIONS

Examiner-in-Chief, _____ Dated, _____

FINAL DECISION

Board of Patent Appeals and Interferences, favorable Dated, 10/31/03

Court, _____ Dated, _____

REMARKS

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This should be placed in each application or patent involved in interference in addition to the interference letters.